

REMARKS

Status of the Claims

Claims 1 – 38 are pending in the application.

Claims 1 –38 have been subject to a restriction requirement.

Claims 19-28 have been deleted, and new claims 39-41 have been added.

Upon entry of this amendment, claims 1-8 and 29-41 will be pending.

Restriction Requirement

Claims 1-38 have been made subject to a restriction requirement. The Office has identified three patently distinct inventions corresponding to the following:

Group I (claims 1-8): subject matter drawn to a cardiac specific-synthetic expression construct;

Group II (claims 9-18 and 29-38): subject matter drawn to a method of using a cardiac specific-synthetic expression construct for expressing a gene in a cardiac cell; and

Group III (claims 19-28): subject matter drawn to a method of making a cardiac specific-synthesis expression construct for expressing a gene in a cardiac cell.

The Office asserts that each group possesses distinct steps and products that require separate and distinct searches. The Office asserts that it would be burdensome to search the inventions of Groups I-III because the inventions of one group use methods and materials not required by the other groups. Applicants traverse.

Applicants assert that, while the Groups may consist of patently distinct subject matter, the subject matter of Groups I and II should be joined because the method of using the subject matter of Group I is so interrelated with its composition, the search of the two groups of invention would not be burdensome. Additionally, the restriction requirement is improperly based on the Groups of inventions being required to contain each and every element of the other groups. The correct standard as to whether the Groups should be subject to a restriction

requirement is whether the groups are materially different. Using a promoter for expression of the gene for which the plasmid encodes is exactly why one would possess the promoter in the first instance. The art related to compositions comprising promoters would relate to art that discloses methods for using such promoters for expression of genes. Therefore, Applicants respectfully urge that Groups I and II be joined.

The Office further asserts that the individual promoter sequences, regulatory elements, and the individual genetic construct sequences are patently distinct. Applicants have added new claims 39-41, which recite linking claims incorporating the sequences identified as synthetic promoter components and cis-acting regulatory elements. Claim 12 recites the use of a cardiac specific synthesis expression construct in which the sequences of promoter sequences and cis-acting regulatory elements are used together. The requirement that a single polynucleotide sequence be chosen among all of the .

Even if the amendment to the claims were not sufficient in overcoming the restriction requirement, the restriction requirement among the individual sequences would still be improper because the sequences share a particular class and subclass. Applicants note that, among each individual sequence identified by the examiner, the sequences are classified under class 536 and subclass 24.1. Additionally, claims 8 and 13 are linking claims that recite combinations of synthetic promoter elements and the cis-acting regulatory elements. Some embodiments of the invention include a promoter comprising SEQ ID NO:5 and the cis-acting regulatory elements of the invention (See, e.g., Figure 1). Therefore separating one promoter sequence into individual components would unnecessarily eliminate combinations of elements of the claims clearly contemplated in the application.

Applicants provisionally elect Group I, SEQ ID NO:5, and SEQ ID NO:1. Applicants reserve the non-elected subject matter for inclusion in a divisional application.

Conclusion

Claims 1-18 and 29-41 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7855 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully Submitted,

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